Appendix G: Summary of MoM Hip Resurfacing Post-Approval Studies

Post-approval studies (PAS) are one mechanism by which FDA can obtain longer-term safety and/or effectiveness data for a device as a condition of approval for a premarket application (PMA), humanitarian device exemption (HDE), or product development plan (PDP) process. However, PAS is not a substitute for obtaining the necessary premarket information to support PMA, HDE, or PDP approval.

The three hip resurfacing systems were approved by FDA and are subject to PAS conditions of approval. The study protocols for each of the conditions of approval are outlined below. All of the information in these tables is available at the PAS public webpage: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm?sb=ms.

P030042 – Conserve Plus Total Resurfacing Hip System – Wright Medical Technology, Inc
There are two PAS conditions of approval for this PMA, the "ConservePlus Longer-Term PAS" and the "ConservePlus New Enrollment PAS." The study plans were approved on July 16, 2010 and June 21, 2010, respectively and both studies are considered to be "Progress Inadequate" due to subject enrollment and site enrollment milestones not being met.

Study Name	**ConservePlus Longer-Term PAS**
Study Design	Prospective Cohort Study
Data Source	New Data Collection
Comparison Group	Historical Control
Study Population	Adult: >21
Study Design Description	Multi-center, prospective, historically controlled
Study Population Description	Patients who were previously enrolled in the CONSERVE Plus Total Resurfacing Hip System IDE
Sample Size	353 patients
Data Collection	The primary endpoint is clinical success at 120 months post-operative for each patient.
Follow-up Visits and Length of Follow-up	Patients will undergo clinical and radiographic evaluation post-operatively at years 5,8, & 10. Patients will also have serum levels of cobalt and chromium ions and renal function data collected postoperatively at years 5, 8, & 10. Length of follow-up: Until each patient has reached 10 years, which will be in 2016.

Study Name	**ConservePlus New Enrollment PAS**
Study Design	Prospective Cohort Study
Data Source	New Data Collection
Comparison Group	Historical Control
Study Population	Adult: >21
Study Design Description	Single-arm, Multi-center cohort
Study Population Description	Patients who have unilateral joint disease
Sample Size	183 patients
Data Collection	Patients will undergo clinical and radiographic evaluation pre-operatively and post operated at 0-60 days, 12, and 24 months.
Follow-up Visits and Length of Follow-up	Patients will undergo clinical and radiographic evaluation pre-operatively and post operated at 0-60 days, 12 and 24 months. Length of follow up: 10 years

P040023 – Birmingham Hip Resurfacing (BHR) System – Smith & Nephew Orthopaedics
There are two PAS conditions of approval for this PMA, the "UK Study" and the "US Study." The study plans were both approved on May 9, 2006 and both studies are considered to be "Progress Adequate."

Study Name	**UK Study**
Study Design	Prospective Cohort Study
Data Source	New Data Collection
Comparison Group	No Control
Study Population	Transitional Adolescent B: 18-21 yrs, Adult: >21
Study Design Description	The study design is a single arm, cohort study.
Study Population Description	Study population is as per device indication. Patients who underwent Birmingham Hip Resurfacing (BHR) System, a metal on metal resurfacing artificial hip replacement system, surgically implanted to replace a hip joint. The BHR System is intended for patients who, due to their relatively younger age or increased activity level may not be suitable for traditional total hip arthroplasty, due to an increased possibility of requiring future ipsilateral hip joint revision.
Sample Size	350 patients
Data Collection	Study endpoints include OSHIP scores and device survival.
Follow-up Visits and Length of Follow-up	At the time of PMA submission, all subjects had passed their 5 year post-implantation anniversary. Subjects will be followed annually through the use of self-assessment questionnaires until they reach 10 years of follow-up. At the ten year interval, a final clinical and radiographic examination will occur in addition to the questionnaire.

Study Name	**US Study**
Study Design	Prospective Cohort Study
Data Source	New Data Collection
Comparison Group	No Control
Study Population	Transitional Adolescent B: 18-21 yrs, Adult: >21
Study Design Description	The study design is a multi-center, single arm, prospective cohort study.
Study Population Description	Study population is as per device indication. Patients who underwent Birmingham Hip Resurfacing (BHR) System, a metal on metal resurfacing artificial hip replacement system, surgically implanted to replace a hip joint. The BHR System is intended for patients who, due to their relatively younger age or increased activity level may not be suitable for traditional total hip arthroplasty, due to an increased possibility of requiring future ipsilateral hip joint revision.
Sample Size	350 patients
Data Collection	Study endpoints include Harris Hip Score and device survival.
Follow-up Visits and Length of Follow-up	Patients will undergo clinical and radiographic examinations for the first five years of follow-up with a final clinical and radiographic examination at 10 years. Subjects will receive annual questionnaire follow-up in years 6 through 9.

P050016 – Cormet Hip Resurfacing System – Corin U.S.A.
There are two PAS conditions of approval for this PMA, the "New Enrollment" and the "Long Term Study." The study plans were both approved on July 3, 2007 and both studies are considered to be "Progress Adequate."

Study Name	**New Enrollment**
Study Design	Prospective Cohort Study
Data Source	New Data Collection
Comparison Group	Historical Control
Study Population	Transitional Adolescent B: 18-21 yrs, Adult: >21
Study Design Description	The study is a multi-center, prospective cohort study. The first null hypothesis of the study is that the 24 month cumulative revision rate is more than 0.126. The second null hypothesis is that the 24 month composite clinical success rate is less than 0.81.
Study Population Description	Study population is as per device indication.
Sample Size	160 procedures
Data Collection	For both primary efficacy endpoints (freedom from revision and composite clinical success), the primary objective will be met by way of estimation using 95% exact binomial confidence intervals. Device survival will be illustrated by life tables and the plotting of a Kaplan-Meier curve.
Follow-up Visits and Length of Follow-up	Patients will be evaluated preoperatively, and at 6 weeks, 6 months, 12 months and 24 , months postoperatively. The length of patient follow-up is two years.

Study Name	**Long Term Study**
Study Design	Prospective Cohort Study
Data Source	New Data Collection
Comparison Group	No Control
Study Population	Transitional Adolescent B: 18-21 yrs, Adult: >21
Study Design Description	The study is a multi-center, non-randomized, cohort study, which includes the extended follow-up of the premarket cohort.
Study Population Description	Study population is as per device indication.
Sample Size	448 patients
Data Collection	Data collection includes patient demographic data and medical history. A functional evaluation will be performed including a Harris Hip Score. Radiographic examination will encompass anteroposterior (AP) and lateral plain film studies.
Follow-up Visits and Length of Follow-up	Patients will receive clinical and radiographic examination at 3, 4, 5, 8 and 10 postoperative years. In addition, patients will receive brief questionnaires at 6, 7, and 9 postoperative years. For both primary efficacy endpoints (freedom from revision and composite clinical success) , the primary objective will be met by way of estimation using 95% exact binomial confidence intervals. Device survival will be illustrated by life tables and the plotting of a Kaplan-Meier curve.